510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k051200

B. Purpose for Submission:

New Device

C. Measurand:

Hemoglobin A1c

D. Type of Test:

Quantitative

E. Applicant:

Teco Diagnostics

F. Proprietary and Established Names:

Hemoglobin A1c Reagent Set
Hemoglobin A1c Calibrator Set
Hemoglobin A1c Control Set

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.7470 – Glycosylated hemoglobin assay
   21 CFR 862.1150 – Calibrator
   21 CFR 862.1660 – Quality control material (assayed and unassayed)

2. Classification:

   Class II - assay
   Class II - calibrator
   Class I reserved – control

3. Product code:

   LCP - assay
   JIS - calibrator
   JJX - control

4. Panel:

   Hematology (81) - reagent
   Chemistry (75) – calibrator and control

H. Intended Use:

1. Intended use(s):

   The Hemoglobin A1c Reagent Set is for the quantitative determination of Hemoglobin A1c (HbA1c) in human blood. The determination of HbA1c is most commonly performed for the evaluation of glycemic control in diabetes mellitus. HbA1c values provide an indication of glucose levels over the preceding 4-8 weeks. A higher HbA1c value indicates poorer glycemic control. For *in vitro* diagnostic use only.

   The Hemoglobin A1c Calibrator Set is for the purpose of calibrating results in the quantitative determination of human hemoglobin A1c (HbA1c) in blood by automated immunoassay. For *in vitro* diagnostic use only.

   The Hemoglobin A1c Control Set is for the purpose of monitoring accuracy and precision in the quantitative determination of human hemoglobin A1c (HbA1c) in blood by automated immunoassay. For *in vitro* diagnostic use only.

2. Indication(s) for use:

   The Teco Hemoglobin A1c Calibrators are for calibrating results in the quantitative determination of human hemoglobin A1c (HbA1c) and the Teco Hemoglobin Controls are for the purpose of monitoring accuracy and precision in the quantitative determination of human hemoglobin A1c (HbA1c). The Teco Hemoglobin A1c Reagent Set is for the quantitative determination of Hemoglobin A1c (HbA1c) in human blood. The determination of HbA1c is most commonly performed for the evaluation of glycemic control in diabetes mellitus. HbA1c values provide an indication of glucose levels over the preceding 4-8 weeks. A higher HbA1c value indicates poorer glycemic control. For *in vitro* diagnostic use only.

3. Special conditions for use statement(s):

   These devices are for prescription use.

4. Special instrument requirements:

   The Hemoglobin A1c Reagent Set, calibrators, and controls are for automated clinical chemistry analyzers. All performance data was determined on the Hitachi 717 analyzer.

I. Device Description:

The Hemoglobin A1c Reagent Set contains the following items: 1 x 30 mL R1, 1 x 9.5 mL R2a, 1 x 0.5 mL R2b, and 1 x 125 mL Lyse. R1 contains latex and glycine buffer. R2a contains glycine buffer. R2b contains mouse anti-human HbA1c monoclonal antibody, goat anti-mouse IgG polyclonal antibody, and stabilizers. The Hemolysis reagent contains water and stabilizers.

The calibrator kit contains 4 x 1 mL vials (Calibrator 1, 2, 3, and 4). The vials contain lyophilized hemoglobin A1c (hemolysate prepared from packed human erythrocytes) and stabilizers.

The control kit contains 2 x 1 mL vials (Control 1 and Control 2). The vials contain lyophilized hemoglobin A1c (hemolysate prepared from packed human erythrocytes) and stabilizers. One control is in the normal range and the other is in the elevated range.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Hemoglobin A1c Reagent Set

2. Predicate 510(k) number(s):

   k031539

3. Comparison with predicate:

Similarities		
Item	Device	Predicates
Intended Use	Quantitative determination of hemoglobin A1c	Same
Specimen	Human blood	Same
Test Principle	Agglutination assay	Same

Differences		
Item	Device	Predicate
Linearity	2-17%	2-16%
Sensitivity	0.5%	1%

K. Standard/Guidance Document Referenced (if applicable):

NCCLS EP5-A – Evaluation of Precision Performance of Clinical Chemistry Devices
NCCLS EP6-P – Evaluation of Linearity of Quantitative Analytical Methods
NCCLS EP9-A – Method Comparison and Bias Estimation Using Patient Samples

L. Test Principle:

This method utilizes the interaction of antigen and antibody to directly determine the HbA1c in whole blood. When mouse antihuman HbA1c monoclonal antibody is added (R2), latex-HbA1c-mouse antihuman HbA1c antibody complex is formed. Agglutination is formed when goat anti-mouse IgG polyclonal antibody interacts with the monoclonal antibody. The amount of agglutination is proportional to the amount of HbA1c absorbed onto the surface of latex particles. The amount of agglutination is measured as absorbance. The HbA1c value is obtained from a calibration curve.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Run-to-run precision was determined following a modification of NCCLS EP5-A. Two commercial controls (levels 1 & 2) were assayed on the Hitachi 717 five times per day for five days. The results were as follows:

	Control 1 (%)	**Control 2 (%)**
Mean	3.94	9.7
SD	0.165	0.275
%CV	4.1	2.8

Within-run precision was determined following a modification of NCCLS EP5-A. Two commercial controls (levels 1 & 2) were assayed 25 times on the Hitachi 717, and the following results were obtained:

	Control 1 (%)	**Control 2 (%)**
Mean	4.0	10.0
SD	0.126	0.269
%CV	3.1	2.7

b. Linearity/assay reportable range:

Linearity studies were designed using NCCLS EP6-P and performed using the Hitachi 717. Serial dilutions of high level whole blood samples were used. Each concentration was tested twice to determine the mean concentration. The results of this study yielded a linearity of 2-17%. The HbA1c values were plotted versus the sample dilution, and an appropriate line fitted by standard linear regression. $Y = 0.92x + 0.45$, $r = 0.996$.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The calibrators and controls are prepared from packed human erythrocytes. These products have been tested and found non-reactive for Hepatitis B Surface Antigen (HBsAG) and HIV.

The setpoint values of the calibrators were obtained by assaying representative samples of the entire lot against NGSP reference materials using a commercially available assay.

The mean values of the controls were obtained by assaying representative samples of the entire lot.

To evaluate stability, the calibrators and controls were reconstituted and stored at 2-8°C in a refrigerator for 35 days. The solutions were tested every 5 days and passed. The reconstituted calibrators and controls are stable for at least 30 days at 2-8°C.

d. Detection limit:

The sensitivity is defined as the concentration that can be distinguished from zero with 95% confidence. The sensitivity of HbA1c reagent was investigated on the Hitachi 717 by reading the change for a saline sample and whole blood sample with a known concentration. The Teco HbA1c Reagent showed little or no reagent drift with the zero sample. The results for the 0.5% sample all fell within the 95% confidence interval. The sensitivity for the method was established as 0.5%.

e. Analytical specificity:

An interference study, to assess common or known substances that could interfere with the method, was conducted according to the procedures recommended in NCCLS EP7. Ascorbic acid, bilirubin, triglyceride, acetylated Hb, and carbamylated Hb were tested for interference. Five samples spiked with the interferent and without the interferent were tested three times. The results showed no significant difference (1-3%) with the potentially interfering substances.

f. Assay cut-off:

See "Detection limit" above.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison study was designed using NCCLS EP9-A. The study was performed on the Hitachi 717 Chemistry Analyzer following instructions for automatic procedure. Forty samples were analyzed by the subject device and the predicate device, and the results were compared. The results from the subject device, with HbA1c ranging from 3.6% to 15.2%, yielded the following regression equation: $y = 0.95x + 0.28$. The correlation coefficient was 0.978.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The recommended values of less than 6% for non-diabetics and less than 7% for glycemic control of persons with diabetes were based on literature.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.